

## Message Text

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ACTION EA-09

INFO OCT-01 ISO-00 AID-05 CEQ-01 CIAE-00 OFA-01 COME-00

DODE-00 EB-07 EPA-01 INR-07 IO-11 L-03 NSF-01 NSC-05

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AGR-05 STR-04 PA-01 PRS-01 /099 W

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R 300900Z JAN 76

FM AMEMBASSY TOKYO

TO SECSTATE WASHDC 6525

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E.O. 11652: N/A

TAGS: ETRD EAGR KA

SUBJECT: CITRUS WAXES AND FUNGICIDES

DEPARTMENT PASS AGRICULTURE FOR FITZSIMMONS

REF: (A) TOKYO 0761 (B) TOKYO 0840 (C) TOKYO AIRCOMM

NO. 36 (3-17-75) (D) FASTO 72 (E) TOFAS 37

1. SUMMARY: AGATT AND ASST HAVE VISITED KEY OFFICIALS IN MAF, MHW AND INSTITUTE OF ENVIRONMENTAL TOXICOLOGY (IET) OVER PAST FIVE DAYS. AS RESULT HAVE LEARNED THAT IET PLANNING BEGIN MUTAGENICITY RESEARCH ON OPP AND TBZ ASAP, FUNDED BY PRIVATE SOURCES. EVERY EFFORT BEING MADE KEEP ISSUE OUT OF PRESS. SOME CONCERN THAT NECESSARY RESEARCH WILL NOT BE COMPLETED IN TIME TO AVOID HIGH SUMMER PRICES FOR LEMONS DUE TO SPOILAGE. PERHAPS SOME SLIGHT POSSIBILITY THAT FOOD SANITATION INVESTIGATION COUNCIL (FSIC) COULD MEET BEFORE COMPLETION OF RESEARCH TO CONSIDER PROVISIONAL APPROVAL IN EFFORT TO AVOID COMPLICATIONS OF SPOILAGE. MHW INSPECTION PROCESS FOR WAXES WILL BE SAME AS IN PAST EXCEPT NON-NATURAL SUBSTANCES MUST BE LISTED EFFECTIVE MARCH 1. END SUMMARY.

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2. AGATT MET WITH MAF DIR GEN SAWABE JAN 26 TO THANK

HIM FOR COOPERATION DURING ASST SEC BELL'S VISIT AND INQUIRE  
RE PROGRESS ON SEVERAL ISSUES INCLUDING OPP/TBZ.

3. SWABE, WHO HAD JUST BEEN BRIEFED BY DR SHIRASU (RECENTLY RETURNED FROM U.S.), STATED THAT MUTAGENICITY RESEARCH WILL PROBABLY BEGIN SOMETIME IN FEB AND MAY TAKE FOUR OR FIVE MONTHS TO COMPLETE. HE ALSO POINTED OUT THAT DR SHIRASU HAD LEARNED THAT EPA WILL, WITHIN ONE YEAR, REQUIRE MUTAGENICITY DATA ON ALL NEW PESTICIDES FOR WHICH REGISTRATION IS REQUESTED AND THAT PROBABLY REPEAT PROBABLY WITHIN SIX YEARS EPA WILL REQUIRE SUCH DATA ON ALL PREVIOUSLY REGISTERED CHEMICALS, INCLUDING OPP AND TBZ. SAWABE SAID, USDA ASKED DR SHIRASU IF MHW COULDNT GIVE PROVISIONAL APPROVAL OF CHEMICALS BEFORE MUTAGENICITY RESEARCH COMPLETED. THIS, HE EXPLAINED, IS MHW PROBLEM BUT UNDER CURRENT LAW PROVISIONAL APPROVAL MAY BE IMPOSSIBLE.

4. MHW FOOD CHEMISTRY SECTION CONTACTED AGATT OFFICE JAN 27 AND REQUESTED (A) TERAROGENICITY DATA ON OPP (NONE EXISTS IN DATA PACKAGE SUBMITTED TO DATE). , (B) ANY ADDITIONAL LONG TERM TOXICOLOGICAL DATA AVAILABLE ON OPP, (ONLY ONE REPORT ON THIS FOUND IN U.S. DATA PACKAGE), (C) ANY ADDITIONAL TERATOGENICITY AND/OR LONG TERM TOXICOLOGY DATA ON TBZ. AGATT TEP EXPLAINED THAT MANY TIMES IN PAST (AS MUCH AS SIX MONTHS AGO) THE FACT THAT TERATOGENICITY DATA FOR OPP WAS NOT INCLUDED IN DATA PACKAGE SUBMITTED BY U.S. HAD BEEN DISCUSSED AND MHW/CHEM GAVE AGATT IMPRESSION DATA'S ABSENCE WAS NOT SERIOUS PROBLEM; DOES THIS NEW REQUEST MEAN MHW CANNOT TAKE OPP TO FSIC WITHOUT TERATOGENICITY DATA? MHW/CHEM REPLIED IT WOULD BE BETTER TO HAVE SAID DATA IF AT ALL POSSIBLE AS FSIC MAY REQUEST IT.

5. AGATT REPS VISITED MHW JAN 28, TO CONFIRM MHW FIVEW RE INSPECTION ON WAXES. WERE ASSURED THAT INSPECTION PROCEDURES WOULD NOT CHANGE AFTER MARCH 1 BUT IF ANY PROHIBITED CHEMICALS LISTED ON IMPORT APPLICATION, WOULD RESULT IN IMPORT BAN ON SHIPMENT INVOLVED. ONLY FILM FORMING AGENTS (CHEMICALS) THAT CAN BE LISTED ON FRESH CITRUS AND STILL GET CUSTOMS CLEARANCE ARE THOSE LISTED REF A. NATURAL WAXES SUCH AS CARNAUBA WAX, OR CALCIUM SALT OF PARTIALLY DIMERIZED ROSIN (POLY-PALE TYPE LIMITED OFFICIAL USE

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WAXES) AND SHELLAC NEED NOT BE LISTED ON IMPORT APPLICATION. MHW HAS NOT "APPROVED" POLY PALE TYPE WAXES, (SINCE THEY ARE NATURAL THEY NEED NOT BE APPROVED). MHW HAS SIMPLY DETERMINED THAT POLY-PALE TYPE WAXES ARE NATURAL.

6. DURING VISIT JAN 28 MHW REAFFIRMED THEIR DESIRE TO RECEIVE TERATOGENICITY DATA ON OPP, IF CURRENT CLIMATE HOLDS, MHW SHOULD HAVE NO DIFFICULTY TAKING OPP TO FSIC WITHOUT SUCH

DATA, BUT IT IS CONCEIVABLE THAT OPPOSITION FSIC MEMBERS OR OTHERS WITH INFLUENCE WILL DEMAND SUCH DATA. MHW REGULATIONS LIST SUCH DATA AS NECESSARY FOR APPROVAL OF NEW FOOD ADDITIVE IF IT IS CONSIDERED POSSIBLE THAT CHEMICAL IN QUESTION COULD CAUSE BIRTH DEFECTS.

7. AGATT REPS MET WITH DR Y. SHIRASU, DIR OF TOXICOLOGY, INSTITUTE OF ENVIRONMENTAL TOXICOLOGY (IET) (TRANSLATED AS "AGRIC CHEMICAL RESIDUE RESEARCH INSTITUTE" IN PREVIOUS CABLES ON MATTER). SHIRASU HAS WORKED THREE YEARS (1963-69 IN U.S. AT NATL INSTITUTE OF HEALTH ON U.S. GOVT GRANT. HE GAVE BRIEF ACCOUNT OF HIS RECENT VISIT TO U.S. RE OPP/TBZ ISSUE, REFERRING TO EPA'S NOTICE PUBLISHED IN FEDERAL REGISTER OF JUNE 25, 1975 RE "HAZARDS TO HUMANS AND DOMESTIC ANIMALS."

8. ACCORDING TO SHIRASU, MUTAGENICITY RESEARCH ON OPP/TBZ WILL BE STARTED ASAP. HE NOW "MAKING THE ROUNDS" TO GET FINANCING FIRMED UP (WILL COST 7-10 MILLION YEN PER CHEMICAL) AND ACQUIRE NECESSARY SAMPLES OF CHEMICALS. HE ASSURES US THERE SHOULD BE NO GREAT CONCERN RE WHETHER CHEMICALS WILL PROVE TO BE MUTAGENS. SAYS HE HAS DONE MUTAGENICITY SCREENING TESTS (USING MICRO-ORGANISMS) ON ABOUT 170 AG CHEMICALS, INCLUDING MANY FUNGICIDES, AND ALTHOUGH SUCH TEST IS VERY SENSITIVE, ONLY 9 OR 10 OF 170 CHEMICALS TESTED POSITIVE. HE BELIEVES WHEN SAID CHEMICALS ARE SUBJECTED TO HIGHER LEVEL TESTS (USING RATS) PROBABLY ALL WILL TEST NEGATIVE (NON-MUTAGENIC).

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9. SHIRASU HOPES TO GET TESTS STARTED BY MID-FEB, AND WILL RUN VARIOUS TESTS IN PARALLEL FASHION TO SAVE TIME. HE THINKS 3 TO 5 MONTHS WILL BE NECESSARY TO COMPLETE TESTS. THEN PERHAPS ONE OR TWO MONTHS FOR FINAL APPROVAL, INCLUDING FSIC REVIEW AND RECOMMENDATIONS.

10. SHIRASU MOST ANXIOUS TO AVOID ANY PUBLICITY ON MATTER, ESPECIALLY WHILE RESEARCH IN PROGRESS. HEAVY SPOILAGE OF FRUIT AND RESULTING HIGH PRICES IN SUMMER COULD LEAD TO TOO MUCH INTEREST ON PART OF PRESS. IN THIS RESPECT, PROVISIONAL APPROVAL LEAK TO WRONG PERSONS, COULD BE VERY COUNTERPRODUCTIVE.

11. SHIRASU IMPLIED THERE IS SERIOUS QUESTION WHETHER CURRENT FOOD SANITATION LAW WILL PERMIT PROVISIONAL APPROVAL UNDER ANY CIRCUMSTANCES, BUT AS RESEARCH PROGRESSED, THERE MAY COME A POINT WHERE PEOPLE IN CHARGE MAY BEEM IT PROPER TO CALL FSIC TOGETHER TO CONSIDER APPROVAL PENDING FINAL RESEARCH REPORT. BUT LAW MAY NOT PERMIT THIS.

12. RE TERATOGENICITY REARCH, SHIRASU WAS AWARE THAT DATA ON OPP IS NOT AVAILABLE. HE SAID HE WOULD DISCUSS MATTER WITH MHW/CHEM AND HE MAY DECIDE TO DO SAID RESEARCH ALONG WITH MUTAGENICITY RESEARCH. HE SAID IT WOULD TAKE 4 TO 6 MONTHS

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TO DO TERATOGENICITY RESEARCH.

13. COMMENTS: AGATT FEELS PROGRESS IS BEING MADE AND THAT U.S. CITRUS INDUSTRY WILL DO WELL TO WAIT PATIENTLY, TAKING EVERY PRECAUTION TO KEEP ISSUE OUT OF PRESS. DR SHIRASU SUGGESTION THAT TERATOGENICITY RESEARCH ON OPP (SAID DATA NOW AVAILABLE ON TBZ) BE DONE PARALLEL TO HIS OPP/TBZ MUTAGENICITY STUDIES MAY BE VERY WISE. CONCEIVABLE THAT WITHOUT SAID DATA EFFORTS TO GET FINAL APPROVAL WITHIN NEXT 5 TO 7 MONTHS COULD BE FOILED AT LAST MOMEMT. FINANCING MAY BE PROBLEM. IF DOW CHEMICAL NOT WILLING TO HELP RE TERATOGENICITY PERHAPS U.S. CITRUS INDUSTRY COULD TAKE MATTER UNDER CONSIDERATION. FUNDS FOR MUTAGENICITY STUDIES (47,000 TO 67,000 DOLLARS) WILL APPARENTLY BE BORNE BY JAPANESE IMPORTERS WITH PROBABLY SOME HELP FROM MERCK/TOKYO. HODGSON

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## Message Attributes

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